

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

THE UNIVERSITY OF PITTSBURGH OF
THE COMMONWEALTH SYSTEM OF
HIGHER EDUCATION,

Plaintiff,

v.

COOK MYOSITE, INC.,

Defendant.

2:22-CV-00717-CCW

OPINION AND ORDER

On September 29, 2023, the Court held a claim construction hearing to resolve three disputed claim terms. The Court will construct the terms according to the below analysis.

I. Background

On July 20, 2023, Plaintiff University of Pittsburgh of the Commonwealth System of Higher Education filed its First Amended Complaint against Defendant Cook Myosite, Inc. for patent infringement. ECF No. 93. On August 3, 2023, Cook filed its response to the First Amended Complaint and a counterclaim against UPitt. ECF No. 103. The parties disagree as to the rightful owner of U.S. Patent No. 8,211,423 (hereinafter, “the ‘423 Patent”) and whether Cook willfully infringed on the protected methods. The ‘423 Patent contains eleven claims that protect a method of isolating muscle-derived stem/progenitor cells (hereinafter, “MDCs”). *See generally* ECF No. 93, Ex. A.

UPitt asserts that Cook is infringing on five of the eleven claims, Claims 7-11. ECF No. 123, Ex. A at 6–17. Known as the asserted claims,¹ they are as follows:

7. A method of isolating an end population of mammalian skeletal muscle-derived progenitor cells (MDCs) comprising:
 - (a) Suspending human skeletal muscle cells in a medium in a first cell culture container for between 30 and 120 minutes thereby producing a cell population of adherent cells and a population of non-adherent cells;
 - (b) decanting the medium and the population of non-adherent cells from the first cell culture container to a second cell culture container;
 - (c) allowing the population of the decanted non-adherent cells in the medium from the first cell culture container to attach to the walls of the second cell culture container for 1-3 days; and
 - (d) isolating the population of cells adhered from the walls of the second cell culture container, thereby, isolating said end population of MDCs.
8. The method of claim 7, wherein the MDCs are subsequently frozen.
9. The method of claim 8, wherein the MDCs are frozen at a temperature below – 30° C.
10. The method of claim 8, wherein the MDCs are frozen at a temperature below – 70° C.
11. The method of claim 8, wherein the MDCs are frozen on dry ice.

ECF No. 93, Ex. A at 44.

On January 30, 2023, the parties identified seven disputed claim terms in their Joint Prehearing Statement and Joint Disputed Claim Terms Chart.² ECF No. 54 at 4–17. In this joint filing, both UPitt and Cook asserted their proposed construction of each disputed term and the corresponding intrinsic evidence. *Id.* The seven disputed terms included: “adherent cells,” “non-adherent cells,” “cells adhered,” “thereby, isolating said end population of MDCs,” “decanting,” “subsequently frozen,” and “cell culture container.” *Id.*

After the parties submitted briefing on each disputed claim term, *see* ECF Nos. 61, 62, 70 and 71, the Court held a claim construction hearing. ECF No. 108. Prior to the hearing, the parties

¹ The remaining claims, Nos. 1-6, are known as the unasserted claims because UPitt does not assert that Cook is infringing on these protected methods.

² The parties originally identified eight disputed claim terms. After a meet-and-confer, the parties agreed to an interpretation of one disputed term, leaving seven claim terms for the Court to resolve. ECF No. 54 at 1.

reached an agreed-upon construction as to four of the seven terms. ECF No. 110. The remaining three disputed claim terms are: “cell culture container,” “decanting,” and “subsequently frozen.”

II. Claim Construction Analysis

A. Legal Standard

Claim construction is a question of law. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015). In defining claim terms, courts first look to the claims themselves. *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 365 F.3d 1299, 1303 (Fed. Cir. 2004). Claim terms “are generally given their ordinary and customary meaning.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The ordinary and customary meaning is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005).

“In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314. Where the meaning is not readily apparent, the unasserted claims and the context in which a claim is used “can be highly instructive” as “terms are normally used consistently throughout the patent.” *Id.*

A person of ordinary skill in the art is “deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Phillips*, 415 F.3d at 1313–14; *GE Lighting Solutions, LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1308–09 (Fed. Cir. 2014) (“[Claim terms] must be construed in light of the specification and prosecution history, and cannot be considered in isolation.”).

The specification is the “single best guide to the meaning of a disputed term,” and is “the primary basis for construing claims.” *Tippmann Engineering, LLC v. Innovative Refrigeration Systems, Inc.*, No. 5:19-cv-00087, 2023 WL 18559, at *3 (Fed. Cir. Jan. 3, 2023) (cleaned up). The specification provides examples of the patent and is intended “to teach and enable those of skill in the art to make and use the invention.” *Teleflex*, 299 F.3d at 1327.

Although the specification guides claim interpretation, courts must not use it to limit the claims themselves. *Phillips*, 415 F.3d at 1323 (explaining that even if a patent describes only a single embodiment, courts must not limit the patent claims to that embodiment unless the patentee has clearly intended to do so). But a claim construction that “excludes a preferred embodiment from the scope of the claim ‘is rarely, if ever, correct.’” *Id.*

Along with the specification, courts also consider the patent’s prosecution history. *Phillips*, 415 F.3d at 1323. The prosecution history can inform the claim meaning by “demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.* The prosecution history, however, “often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *Id.*

Finally, courts may consider extrinsic evidence, such as expert testimony, dictionaries, and treatises, but “such evidence is generally of less significance than the intrinsic record.” *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1316 (Fed. Cir. 2014) (citations omitted). When considering extrinsic evidence, courts cannot use it “to contradict claim meaning that is unambiguous in light of the intrinsic evidence.” *Phillips*, 415 F.3d at 1324. Usually, the “intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.” *Vitronics*, 90 F.3d at 1583.

B. Claim Construction of the Disputed Terms

i. Cell Culture Container

UPitt contends that “cell culture container” is “a container used for culturing cells.” ECF No. 54 at 15. Cook counters that this disputed term includes any “container used in the process of culturing cells.” *Id.* The Court agrees with UPitt’s construction and will interpret “cell culture container” to mean “a container used for culturing cells.” This meaning most closely aligns with the patent’s intrinsic evidence.

The patent’s claim language, while failing to define “cell culture container,” is informative. In both the asserted and unasserted claims, the words “first” or “second” always precede “cell culture container,” indicating that only two cell culture containers are used throughout the patented process. ECF No. 93, Ex. A at 44; *see Phillips*, 415 F.3d at 1314 (“[T]he context in which a term is used in the asserted claim can be highly instructive . . . the claim in this case refers to ‘steel baffles,’ which strongly implies that the term ‘baffles’ does not inherently mean objects made of steel.”). Furthermore, the only instance in which the claims refer to cell culture containers is when the containers hold the cell culture for 30-120 minutes and for 1-3 days while the cells attach. ECF No. 93, Ex. A at 44 (see Claim 7). Based on this language, the Court concludes that there are only two cell culture containers used in the patented process, and they are used to hold the cell culture for 30-120 minutes and 1-3 days. Therefore, the Court finds that Cook’s interpretation—that *any* container used in the patented process is a cell culture container—contradicts the claim language because the patented process requires the use of multiple containers to hold cell culture at some point but only specifies the use of two “cell culture containers.”

Acting as a person of ordinary skill in the art of cell biology,³ the Court next looks to Example 10 of the specification. ECF No. 93, Ex. A at 40–42. Example 10 provides for the use of multiple instruments that hold the cell culture at some point in the patented process, including collagen-coated plates, T-25 flasks, conical tubes, Eppendorf tubes, and incubators. *Id.* Because there are more than two containers used, the Court determines that not all are cell culture containers; to find otherwise would contradict the plain claim language—that there is a “first” and a “second” cell culture container. Furthermore, only the T-25 flasks and collagen-coated plates are used to hold the cell culture for 30-120 minutes and 1-3 days, indicating that only these instruments are considered cell culture containers. ECF No. 93, Ex. A at 40.

The prosecution history further supports the Court’s interpretation. Initially, the U.S. Patent Office objected to the term “cell culture container” because only one example was provided: a collagen-coated plate. ECF No. 61, Ex. E at 221, 443. In response, the patentee pointed out that the patent referred to both a collagen-coated plate and a T-25 flask as examples of “cell culture containers.” ECF No. 61, Ex. E at 221. The Patent Office then withdrew its objection, implying that T-25 flasks and collagen-coated plates provided sufficient examples of cell culture containers. The fact that neither the patentee nor the Patent Office referred to other instruments mentioned in the specification, such as conical tubes or Eppendorf tubes, as examples of cell culture containers, indicates that no one considered such instruments to be a cell culture container.

Meanwhile, Cook’s proposed definition—that a cell culture container is *any* container used in the process of culturing cells—does not align with the intrinsic evidence as it either contradicts the claim language or negates Example 10. For example, interpreting “cell culture container” to mean “any container that holds cell culture” would, under Example 10, include T-25 flasks,

³ At the claim construction hearing, both parties agreed that the Court should interpret the patent through the lens of a person of ordinary skill in the art of cell biology. ECF No. 117 at 24, 42.

collagen-coated plates, conical tubes, Eppendorf tubes, and incubators because they all contain cell culture at some point in the process. ECF No. 93, Ex. A at 41–42. And because more than two containers are used in Example 10, Cook’s contention that all such containers are “cell culture containers” contradicts the claim language that only two containers are used. Alternatively, if Cook maintains that any container used in the patented process is a “cell culture container” and, aligning with the claim language, concedes that only two cell culture containers are used in the process, its interpretation would contradict Example 10 and its use of multiple instruments to hold cell culture during the process. Therefore, such an interpretation would negate Example 10, a preferred embodiment, which is “rarely, if ever, correct.” *Globetrotter Software*, 362 F.3d at 1381.

Because the intrinsic evidence resolves the meaning of “cell culture container,” the Court need not consider extrinsic evidence. *See Vitronics*, 90 F.3d at 1583 (holding that where “intrinsic evidence alone will resolve any ambiguity . . . it is improper to rely on extrinsic evidence”). Therefore, the Court interprets “cell culture container” to be “a container used for cell culturing” because it most closely aligns with the claim language, specification, and prosecution history.

ii. Subsequently Frozen

UPitt contends that “subsequently frozen” means “subsequently at a temperature that is below the[] freezing point” which includes “both a process step and a static state of matter.” ECF No. 54 at 12; ECF No. 61 at 11. In response, Cook defines this term as only including the process of “subsequently cooling to change from an unfrozen state to a frozen one.” ECF No. 54 at 12. The Court agrees with Cook’s construction and will interpret “subsequently frozen” to mean “the process of cooling to change from an unfrozen state to a frozen one.” Such a definition most closely aligns with the patent’s intrinsic evidence.

The claim language, while failing to define “frozen,” provides instructive context. For example, in unasserted Claim 6, it states that cells “are frozen” after isolation and then “thawed” prior to their use in mammals. ECF No. 93, Ex. A at 44. The use of both “frozen” and “thawed” indicates that the claim covers both the process of freezing and the process of thawing. Furthermore, this language also implies that the claim includes a temporal element, spanning the time during which the MDCs enter a frozen state until they leave that state.

In contrast, asserted Claim 8 directs that the MDCs be “subsequently frozen,” but it does not include the “thawed” language from Claim 6. ECF No. 93, Ex. A at 44. The absence of such language indicates that Claim 8 has a narrower scope than Claim 6. *See Philips*, 415 F.3d at 1314 (explaining that unasserted claims “can be highly instructive” in defining a disputed term as “terms are normally used consistently throughout the patent”). Without specifying that the MDCs are “frozen” and then “thawed,” the temporal element present in Claim 6 is missing in Claim 8.

Furthermore, Claims 8-11 state the temperature at which the MDCs should be frozen but do not include a duration for how long they should be frozen. ECF No. 93, Ex. A at 44. The choice to specify a freezing point but not a length of time to freeze the cells further indicates that Claim 8 does not include a temporal element, but merely covers the process of freezing the cells to a certain temperature.

Turning to the specification, particularly Example 10, the Court finds that it supports limiting “subsequently frozen” to the process of freezing. ECF No. 93, Ex. A at 40–42. The specification explains that after the MDCs are isolated, they are “packaged in the appropriate vial for cryogenic storage,” the “cryovial is placed into a freezing container,” which is then “placed in the -80° C. freezer.” *Id.* at 41. It then explains that the cells are “administered by thawing the frozen cell suspension at room temperature. . .” *Id.* These steps align with unasserted Claim 6

where the MDCs are “frozen” and then “thawed” prior to their “administration” in mammals. *Id.* at 44. Claim 8, however, omits the steps of thawing and administering the MDCs. *Id.* at 44.

The presence of language regarding the freezing of MDCs until thawing and administration in both the unasserted claims and the specification indicates that the patentee knew how to cover both the process of freezing, the state of being frozen, and the process of thawing, but chose not to in Claim 8. The Court will not import a definition onto Claim 8 where the patentee declined to do so. Furthermore, the Court finds that nothing in the prosecution history contradicts this interpretation. Additionally, because the intrinsic evidence resolves any ambiguity in the meaning of “subsequently frozen,” the Court need not consider extrinsic evidence. *See Vitronics*, 90 F.3d at 1583.

Therefore, the Court interprets “subsequently frozen” to mean “the process of cooling to change from an unfrozen state to a frozen one” because it most closely aligns with the patent’s intrinsic evidence.

iii. Decanting

UPitt contends that “decanting” means “transferring the medium and the population of non-attached cells from one cell culture container to another cell culture container.” ECF No. 54 at 9. Cook counters that the meaning of “decanting” is limited to “pouring off liquid from a first cell culture container to a second cell culture container.” ECF No. 54 at 9. The Court agrees with Cook’s construction and will interpret “decanting” to mean “pouring off liquid from a first cell culture container to a second cell culture container.” Such a definition comports with the claim language’s plain and ordinary meaning as understood by a person of ordinary skill in the art.

The claim language, while it does not define “decant,” is instructive. Claim 7(b) refers to “decanting the medium and the population of non-adherent cells.” ECF No. 93, Ex. A at 44. The

Court finds that the plain and ordinary meaning of “decanting” is the separating of a liquid from a sediment by pouring. Because the claim term’s ordinary meaning as understood by a person of ordinary skill in the art is “readily apparent,” the Court will adopt this definition. *See Philips*, 415 F.3d at 1314.

Furthermore, the Court determines that the specification and prosecution history support adopting the plain and ordinary meaning of “decanting.” After reading the claim language, a person of ordinary skill would then turn to the specification to understand how to apply the patented methods in practice. *See GE Lighting Solutions*, 750 F.3d at 1308–09. The specification never refers to “decanting” or “pouring.” ECF No. 93, Ex. A at 29–42. Instead, it directs a person of ordinary skill to “transfer” or “remove” the cell culture from the first container to the second. *Id.* at 40–42. Here, the specification’s use of these words does not contradict the claim language. Instead, a person of ordinary skill would understand that she is to transfer or remove the cell culture from one container to the other by pouring. Further, there is no clear disavowal of the plain and ordinary meaning of “decanting” in the specification nor in the prosecution history. *Lambeth Magnetic Structures, LLC v. Seagate Tech. (US) Holdings, Inc.*, No. 16-538, 2017 WL 46813258, at *3 (W.D. Pa. Oct. 18, 2017) (Bissoon, J.) (explaining that to override a term’s plain and ordinary meaning, the patentee must have “clearly, unambiguously and unmistakably disclaimed or disavowed the proposed interpretation during prosecution”).

Additionally, extrinsic evidence supports Cook’s definition of “decanting.” The Court looks to the Oxford Dictionary of Biochemistry and Molecular Biology, published in 2006, because it is in the relevant field and was published at the time the patent application was filed. *See Kennametal Inc. v. Sandvik, Inc.*, No. 2:09-cv-857, 2010 WL 11579098, at *11, fn. 6 (W.D. Pa Sep. 28, 2010) (McVerry, J.) (explaining that defendant’s extrinsic evidence was inappropriate

because it post-dated the patent application filing date); *Massachusetts Institute of Technology & Electronics for Imaging, Inc. v. Abacus Software*, 462 F.3d 1344, 1351 (Fed. Cir. 2006) (looking to dictionary definitions at the time the patent application was filed). This dictionary defines “decant” as “to pour off a supernatant liquid from a precipitate or other sediment.” OXFORD DICTIONARY OF BIOCHEMISTRY AND MOLECULAR BIOLOGY (Richard Cammack, et al. eds., 2nd ed. 2006). Furthermore, Cook points to several dictionary definitions of decant that refer to the “pouring” of a liquid to separate it from a sediment. ECF Nos. 62 at 15; 62-5, 62-6, 62-11, 62-12. Although the definitions cited by Cook are less instructive because they come from more general dictionaries, instead of dictionaries in the field of cell biology, the Court concludes that the extrinsic evidence supports Cook’s definition of “decanting.”

Therefore, the Court interprets “decanting” to mean “pouring off liquid from a first cell culture container to a second cell culture container.”

III. Conclusion

Accordingly, IT IS HEREBY ORDERED THAT the disputed claim terms are construed as follows:

1. **“Cell culture container” means “a container used for culturing cells.”**
2. **“Subsequently frozen” means “the process of cooling to change from an unfrozen state to a frozen one.”**
3. **“Decanting” means “pouring off liquid from a first cell culture container to a second cell culture container.”**

DATED this 8th day of December, 2023.

BY THE COURT:

/s/ Christy Criswell Wiegand
CHRISTY CRISWELL WIEGAND
United States District Judge

cc (via ECF email notification):

All Counsel of Record